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Dated: 4/14/03 Signature: Anna P. Lucey  
(Anna P. Lucey)

3763  
#10  
Docket No.: BVTP-P04-506  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Allen et al.

Application No.: 10/010723

Group Art Unit: 3763

Filed: December 6, 2001

Examiner: Thompson, Kathryn L.

For: MICRONEEDLE DEVICES AND METHODS  
OF MANUFACTURE AND USE THEREOF

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
Washington, DC 20231

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Pursuant to 37 CFR 1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached Form PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Rejection or Notice of Allowance.

This is Part Two of a two-part Information Disclosure Statement. Part One, citing U.S. Patent art, was filed electronically on the above signed date. The fee of \$180.00 set forth under 37 C.F.R. 1.17(p) was paid online with Part One.

Those patent(s) or publication(s) which are not marked with an asterisk (\*) on the attached Form PTO/SB/08 are not supplied because they were previously cited by or submitted to the Office in prior application no. 09/316,229 filed 05/21/1999, now PAT 6,334,856 which is relied upon in this application for an earlier filing date under 35 U.S.C. 120.

While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents should one or more of the documents be applied against the claims of the present application.

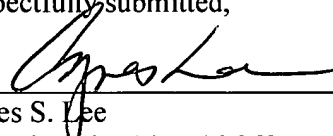
The Commissioner is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 18-1945, under Order No. BVTP-P04-506.

Dated:

4/11/03

Respectfully submitted,

By



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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/010723	
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			First Named Inventor	Mark G. Allen	
			Art Unit	3763	
			Examiner Name	Thompson, Kathryn L.	
Sheet	1	of	4	Attorney Docket Number	BVTP-P04-506

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	AA	2,893,392	07/07/1959	Wagner et al.	
	AB	3,034,507	05/15/1962	McConnell et al.	
	AC	3,086,530	04/23/1963	Groom	
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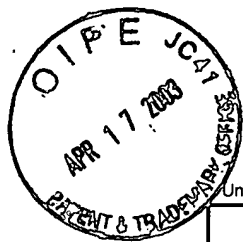
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	BQ	EP 0497620	05/08/1992	Carnegie-Mellon University		
	BR	EP 0 652 600	5/1995			
	BS	JP 7132119	05/23/1995	Nikon Corp.		
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	BU	WO 93/17754	09/16/1993	Elan Medical		
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	BX	WO 96/41236	12/19/1996	Regents of the University of CA		
	BY	WO 97/07734	03/06/1997	Spectrx, Inc.		
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	CA	WO 98/00194	01/08/1998	Sontra Medical		
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	*CC	WO 00/48669	08/24/2000	Biovalve Technologies		
	*CD	WO 00/74763	12/14/2000	Georgia Tech Research		

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
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	*CI	Clarke, M.S.F. and McNeil, P.L. Syringe loading introduces macromolecules into living mammalian cell cytosol. J. Cell. Sci. 102, 533-541 (1992).	
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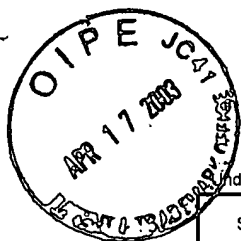
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	*CL	Eleventh Annual International Workshop on Micro Electro Mechanical Systems, Heidelberg, Germany (25-29 Jan. 1998). IEEE Catalog No. 98CH36176	
	CM	Frazier, A.B. and Allen, M.G. Metallic Microstructures Fabricated Using Photosensitive Polyimide Electroplating Molds. J. Microelectromechanical Systems 2, 87-94 (June 1993).	
	CN	Frazier, A.B. et al. Two Dimensional Metallic Microelectrode Arrays for Extracellular Stimulation and Recording of Neurons. IEEE 0-7803-0957 pp. 195-200 (Feb. 1993).	
	CO	Haga et al. Transdermal Iontophoretic delivery of insulin using a photoetched microdevice. J. Controlled Release 43, 139-149 (1997).	
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	CR	Henry, S. et al. Micromachined Needles: A Novel Approach to Transdermal Drug Delivery. J. Pharm. Sci. 87, 922-925 (Aug. 1998).	
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	CX	Langer, R. Drug delivery and targeting. Nature 392 Supp, 5-10 (30 April 1998).	
	CY	Lehmann, V. Porous Silicon - A New Material for MEMS. IEEE ISBN: 0-7803-2985-6/96 (1996).	
	CZ	Lin, L. et al. Silicon Processed Microneedles. The 7 <sup>th</sup> International Conference on Solid-State Sensors and Actuators (1993).	
	DA	Martin, C.R. et al. Template Synthesis of Organic Microtubules. J. Am. Chem. Soc. 112, 8976-8977 (1990).	

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Sheet	4	of	4	Attorney Docket Number	BVTP-P04-506

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DD	<u>Percutaneous Absorption</u> , R.L. Bronaugh and H.I. Maibach, eds. Marcel Dekker, Inc., New York (1989).	
DE	Prausnitz, M.R. Reversible Skin Permeabilization for Transdermal Delivery of Macromolecules. Critical Reviews in Therapeutic Drug Carrier Systems 14, 455-483 (1997).	
DF	Proceedings of the IEEE Micro Electro Mechanical Systems Conference 1987-1998; Rai-Choudhury, ed., Handbook of Microlithography, Micromaching & Microfabrication (SPIE Optical Engineering Press, Bellingham, WA 1997).	
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DL	Talbot, N.H. and Pisano, A.P. Polymolding: Two Wafer Polysilicon Micromolding of Closed-Flow Passages for Microneedles and Microfluidic Devices. Solid-State Sensor and Actuator Workshop, Hilton Head Island, SC (8-11 June 1998).	
DM	<u>Transdermal Drug Delivery</u> , J. Hadgraft and R.H. Guy, eds. Marcel Dekker, Inc., New York (1989).	
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DO	Weber, L. et al. Micro molding – a powerful tool for the large scale production of precise microstructures. SPIE No. 0-8194-2277-0/96, Vol. 2879, p.156-167 (1996).	
DP	Zuska, P. Microtechnology Opens Doors to the Universe of Small Space. MD&DI (1997).	

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